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**DuaneMorris®**

*FIRM and AFFILIATE OFFICES*

SHEILA RAFTERY WIGGINS  
DIRECT DIAL: +1 973 424 2055  
PERSONAL FAX: +1 973 556 1486  
E-MAIL: SRWiggins@duanemorris.com

[www.duanemorris.com](http://www.duanemorris.com)

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November 3, 2017

**VIA ECF**

Honorable Kevin McNulty, U.S.D.J.  
United States District Court - District of New Jersey  
MLK, Jr. Building & U.S. Courthouse  
50 Walnut Street, Room 4015  
Newark, NJ 07101

**Re: BTG International Limited, et al. v. Actavis Laboratories Fl, Inc., et al.  
Civil Action No.: 2:15-cv-05909 (KM-JBC)**

Dear Judge McNulty:

This firm, along with the law firm of Sterne, Kessler, Goldstein & Fox, PLLC, represents Defendants Wockhardt Bio AG, Wockhardt USA, LLC and Wockhardt Ltd. (collectively, "Wockhardt"). We submit this letter in lieu of joining the Motion for Summary Judgment of Noninfringement filed by other Defendants today.

While Wockhardt does not join in the other Defendants' Motion, Wockhardt respectfully submits that, should the Court grant that motion and rule that the moving Defendants' proposed FDA labeling does not infringe U.S. Patent No. 8,822,438, then Wockhardt also would not infringe under the doctrine of collateral estoppel as a matter of law. Should that scenario arise, Wockhardt will seek appropriate relief from the Court.

Defendants' Motion for Summary Judgment of Noninfringement asserts that there can be no infringement because the proposed labeling for their respective proposed ANDA products will not induce or contribute to infringement. If the Court rules for the moving Defendants, then each element of collateral estoppel would be met, whereby precluding Plaintiffs from asserting infringement against Wockhardt as a matter of law because Wockhardt's proposed labeling is substantively identical to the moving Defendants' labeling. As such, the Court's determination on

DUANE MORRIS LLP A DELAWARE LIMITED LIABILITY PARTNERSHIP

GREGORY R. HAWORTH, RESIDENT PARTNER

ONE RIVERFRONT PLAZA, 1037 RAYMOND BLVD., SUITE 1800  
NEWARK, NJ 07102-5429  
DM2/8304168.1

PHONE: +1 973 424 2000 FAX: +1 973 424 2001

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Defendants' Motion for Summary Judgment would be controlling as to Wockhardt because: (1) the previous determination would have been necessary to the decision; (2) the identical issue would have been previously decided; (3) the issue would have actually been decided on the merits and the decision would be final and valid; and (4) Janssen, the party being precluded from re-litigating the issue, would have been adequately represented in the previous action. *See Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d. Cir. 2006); *Novartis Pharms. Corp. v. Abbott Labs.*, 375 F.3d 1328, 1333 (Fed. Cir. 2004).

Should the Court have any questions, we are available at Your Honor's convenience.

Respectfully submitted,  
/s/ Sheila Raftery Wiggins  
Sheila Raftery Wiggins

SRW/da

cc: All counsel (via ECF)